Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Blanche M. Manning	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	00 C 2855	DATE	April 3, 2002
CASE TITLE	*Smithkline Beecham v. Pentech*		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] Asahi and Pentech's motion for summary judgment is denied. To preserve the confidentiality of certain information, the court has prepared a public memorandum as well as a sealed version containing proprietary materials. Sentences in the sealed version which differ from the public version have been italicized. Enter Memorandum under seal and Memorandum and Order.

(11) ■ [For further detail see orders attached to the original minute order.]

	No notices required, advised in open court.		number of notices
	No notices required.		
✓	Notices mailed by judge's staff.	APR 10 2002	date docketed
	Notified counsel by telephone.	UMD	docketing deputy initials
	Docketing to mail notices.		
	Mail AO 450 form.		date mailed notice
✓	Copy to judge/magistrate judge.		
RTS	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials

Document Number 172

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SMITHKLINE BEECHAM CORPORATION and BEECHAM GROUP, p.l.c., Plaintiffs,	)	
v.	)	00 C 2855
PENTECH PHARMACEUTICALS, INC. and ASAHI GLASS CO., LTD. Defendants.	)	
SMITHKLINE BEECHAM CORPORATION and BEECHAM GROUP, p.l.c., Plaintiffs,	)	
v.	)	
PENTECH PHARMACEUTICALS, INC. and ASAHI GLASS CO., LTD. Defendants.	)	

MEMORANDUM AND ORDER

Plaintiffs SmithKline Beecham Corporation and Beecham Group, p.l.c. (collectively, "SB") claim that defendants Pentech Pharmaceuticals, Inc. ("Pentech") and Asahi Glass Company, Ltd. ("Asahi") infringed four patents that SB holds relating to its drug Paxil®,[1] an anti-depressant that is among the most widely prescribed prescription drugs in the United States. Pursuant to Federal Rule of Civil Procedure 56(c), defendants Pentech and Asahi have filed a motion for summary judgment. They claim that it is undisputed that Asahi did not induce Pentech to infringe SB's patents in violation of 35 U.S.C. § 271(b). For the following reasons, the court disagrees.

[1] For the court's convenience, the ® will be omitted from subsequent references to Paxil.

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I. Background

SB's Paxil pharmaceutical product contains the active ingredient crystalline paroxetine hydrochloride. Pentech has been developing a new drug containing a form of the active ingredient paroxetine hydrochloride. The Food and Drug Administration has not approved the use of paroxetine hydrochloride for the condition Pentech's drug is meant to treat (referred to herein as "the non-approved indication"). A crystalline form of a chemical compound is a solid that is arranged in a highly ordered fashion which gives a distinctive X-ray diffraction pattern. SB claims that the form Pentech says it will sell is inherently unstable and tends to convert to crystalline forms, so that Pentech's drug will either contain infringing forms of paroxetine hydrochloride or will convert to infringing crystalline forms.

In February of 1997, Pentech signed an agreement with Asahi wherein Asahi agreed to supply Pentech with a form of bulk paroxetine hydrochloride for its use in filing a New Drug Application ("NDA") for its drug for the non-approved indication.[2] SB asserts that this agreement required Asahi to do more than simply supply Pentech with a form of bulk paroxetine hydrochloride. It claims that Pentech and Asahi eventually agreed to jointly develop a paroxetine drug to treat depression and that Asahi agreed to prepare and file a Drug Master File ("DMF") with the FDA and provide technical information that could be used for drug applications other than the non-approved indication.[3] On the other hand, the defendants claim

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[2] An NDA is an application filed with the FDA which covers a new drug or a new use for an already known and approved drug. 21 C.F.R. § 314.50.

[3] A DMF is "a submission of information to the [FDA] by a person (the drug master file holder) who intends it to be used for one of the following purposes: To permit the holder to incorporate the information by reference when the holder submits an investigational new drug application . . . or submits an application or an abbreviated application or an amendment or supplement to them under this part, or to permit the holder to authorize other persons to rely on the information to support a submission to [the] FDA without the holder having to disclose the information to the

that the agreement only allowed Pentech to use the technical information for the NDA for the drug for the non-approved indication.

According to the defendants, Pentech independently decided to develop a generic anti-depressant containing a form of paroxetine hydrochloride based on SB's drug Paxil, which, as noted above, contains crystalline paroxetine hydrochloride. The defendants assert that Pentech then planned to file an Abbreviated New Drug Application (ANDA) with the FDA for its generic anti-depressant before it filed the NDA on its drug for the non-approved indication. In contrast, SB alleges that both Pentech and Asahi decided to file the ANDA for an anti-depressant.

After either Pentech (as the defendants claim) or Pentech and Asahi (as SB claims) decided to file the ANDA for an anti-depressant, Pentech sought to amend the agreement with Asahi to allow Asahi to develop the active ingredient necessary to support the ANDA. The defendants claim that Asahi initially refused to allow the amendment but eventually allowed it after months of pressure from Pentech. SB claims, to the contrary, that Asahi agreed to the amendment without qualification or hesitation. The amendment was finalized in early 1998, when Pentech and Asahi executed an addendum which permitted the use of Asahi's amorphous paroxetine hydrochloride in the ANDA for an anti-depressant.

In May of 1998, Dr. Yasuda of Asahi sent Pentech a letter requesting that the addendum be cancelled so that the parties would be back to working together to develop paroxetine hydrochloride into a drug for the non-approved indication. The defendants claim that Pentech ultimately persuaded Asahi to proceed with the agreement as amended with the understanding that Pentech, not Asahi, would file any ANDA directed at a generic form of paroxetine hydrochloride drug to treat depression.

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person." 21 C.F.R. § 314.420.

SB contends that Dr. Yasuda's letter was a mere proposal to alter the agreement back to its original form. SB further contends that, after a telephone conversation the day that letter was sent, Dr. Yasuda sent another letter stating that Asahi would continue with the work for the ANDA. In addition, SB asserts that Asahi was never concerned with who would file the ANDA. In fact, SB claims that Asahi and Pentech met to discuss the ANDA and that they intended to use it to precipitate an infringement suit with SB over Paxil. In essence, the parties dispute whether Asahi ever tried to back out and whether Asahi knew or intended to participate in the preparation of the ANDA for the ANDA for a generic anti-depressant.

The defendants also claim that Asahi learned that an ANDA had been filed in May of 2000. In contrast, SB claims that Asahi knew about the impending filing of the ANDA much earlier and had even submitted a letter of authorization to the FDA in October of 1999, which gave the FDA permission to use Asahi's DMF.

The defendants further state that Asahi did not know that Pentech was using some of Asahi's paroxetine hydrochloride in clinical studies to support Pentech's ANDA. SB disagrees, asserting that Asahi knew that one particular shipment of paroxetine hydrochloride would be used in a study because, unlike all previous shipments, the shipment label did not contain a "not for clinical use" restriction.

II. Discussion

The defendants' motion for summary judgment turns on whether Asahi induced Pentech to infringe SB's Paxil patents in violation of 35 U.S.C. § 271(b). For the following reasons, the court finds that factual disputes preclude the court from resolving this issue at this stage in the proceedings.

A. Standard for Summary Judgment

Summary judgment is proper when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The party opposing the summary judgment motion "may not rest upon the mere allegation or denials of the adverse party's pleading"; rather, it must respond with "specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Valenti v. Qualex, Inc.*, 970 F.2d 363, 365 (7th Cir. 1992), *citing Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A court should grant a motion for summary judgment only when the record shows that a reasonable jury could not find for the nonmoving party. *Valenti v. Qualex, Inc.*, 970 F.2d at 365; *Anderson v. Liberty Lobby, Inc.*, 477 U.S. at 248.

B. Inducement of Infringement under 35 U.S.C. § 271(b)

35 U.S.C. § 271(b) provides that, "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Liability under § 271(b) attaches if a party "actively and knowingly aid[s] and abet[s] another's direct infringement." *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 668, (Fed. Cir. 1988). This means that an alleged infringer is liable if: (1) it knowingly acts; and (2) specifically intends to aid in the infringement. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir.1990).

With respect to the first prong, the plaintiff bears the burden of proving that the party who allegedly induced infringement knew about the direct infringer's actions. *Id.* Knowledge in the context of inducing infringement means knowingly, in the sense of purposeful and intentional, as distinguished from accidental or inadvertent. *Tegal Corp. v. Tokyo Electron Co.,*

Ltd., 248 F.3d 1376, 1378-79 (Fed. Cir. 2001). It also means that, to be liable, an alleged inducer must have known or should have known that its actions would induce actual infringement. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d at 553.

With respect to the second prong, the plaintiff must establish that the alleged infringer specifically intended to aid and abet the direct infringer. *Id.* Specific intent must be based on more than a showing that "the defendant had knowledge of the acts alleged to constitute inducement." *Id.* at 554. Instead, the plaintiff must show that the alleged infringer specifically intended to encourage the party committing the direct infringement to engage in its wrongful actions. *Id.*

The plaintiff must also establish that the allegedly infringing party engaged in some type of affirmative action in furtherance of the infringing acts. *Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d at 1378. "In the absence of a showing of control over another party, merely permitting that party to commit infringing acts does not constitute infringement" or the facilitation of infringement. *Id.* at 1379.

So, did Asahi knowingly and intentionally commit any affirmative acts in an effort to cause Pentech to infringe any of SB's Paxil patents? The court cannot answer this question because precisely what Asahi knew, intended, and did are hotly disputed. First, the parties point to conflicting evidence regarding the scope of the agreement between Pentech and Asahi. SB claims that under both the original and amended agreements, Asahi agreed to participate in filing the ANDA for a medication to treat depression as well as the non-approved indication. SB also asserts that Asahi and Pentech jointly agreed to file the ANDA for a drug to treat depression. The defendants point to conflicting evidence.

Second, with respect to the amended agreement, the defendants assert that Asahi initially resisted allowing a change to permit the use of paroxetine hydrochloride in drugs meant to treat disorders besides the non-approved indication. The defendants also maintain that, after the amendment was signed, Asahi tried to change the agreement back to permit the use of paroxetine hydrochloride only to treat the non-approved indication. The defendants also state that Pentech had to convince Asahi to continue with the amended agreement. SB, on the other hand, claims that Pentech never had to convince Asahi to continue with the amended agreement.

Third, the parties disagree as to whether Asahi knew that amending the agreement to cover the use of paroxetine hydrochloride to treat depression would lead to an infringement suit from SB. According to the defendants, Asahi only continued with the amended agreement because Pentech agreed that it, not Asahi, would file the ANDA for a drug to treat depression. The defendants further claim that Pentech alone decided to file the ANDA for a drug to treat depression. According to SB, however, Asahi knew all along that an ANDA filed for a drug to treat depression would lead to an infringement action and that Asahi nevertheless made a joint decision with Pentech to file the ANDA.

Finally, the parties disagree as to Asahi's knowledge regarding Pentech's use of Asahi's paroxetine hydrochloride in Pentech's bioequivalency studies necessary to develop its depression drug for the ANDA. The defendants claim that Asahi did not know that the active ingredient it shipped would be used for the studies, while SB asserts that shipping label changes for a particular shipment show that Asahi knew and intended to have its form of paroxetine hydrochloride used in Pentech's study.

In short, when the court views the evidence in the light most favorable to the nonmoving party (here, SB) and draws all reasonable inferences in its favor, it must conclude that summary

judgment is inappropriate. The facts outlined above are material and disputed and preclude any definitive findings with respect to whether Asahi induced infringement in violation of 35 U.S.C. § 271(b).

III. Conclusion

For the above reasons, Asahi and Pentech's motion for summary judgment is denied.

DATE: APR 03 2002

Blanche M. Manning
Blanche M. Manning
United States District Judge

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